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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,710	04/22/2005	Takeshi Ito	KUZ-0022	5270

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09/11/2009

EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1619

MAIL DATE	DELIVERY MODE
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09/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/527,710		ITO ET AL.	
	Examiner		Art Unit	
	SHANON A. FOLEY		1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2009 has been entered.

Applicant has amended claims 1 and 8, cancelled claims 6 and 7 and added new claims 11-19. Claims 1-5 and 8-19 are pending and under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 states that the pressure-sensitive adhesive layer **consists of** fentanyl, a pressure-sensitive adhesive base, a percutaneous absorption enhancer and a tackifier resin (emphasis added). In paragraphs [0023, 0040, 0041] of the instant published disclosure (USPgPub 2007/0009588), percutaneous absorption enhancers are listed as genus compounds, such as fatty alcohols, ethers, aromatic alcohols, as well as specific compounds (recited in instant claim 9). Since the number and type of percutaneous absorption enhancers are non-limiting in claims 8 and 13-19, and the genus of compounds taught in the instant disclosure in paragraphs [0040 and

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0041] could perform various functions beyond enhancing percutaneous absorption in the pressure-sensitive adhesive layer, it cannot be determined which specific ingredients are consisting within the pressure-sensitive adhesive base.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 9 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 8 requires that the pressure-sensitive adhesive layer **consists of** fentanyl, a pressure-sensitive adhesive base, a percutaneous absorption enhancer and a tackifier resin (emphasis added). It is noted that the language "consisting of" first appeared in the amendment filed on September 5, 2008. Support for the amendment is said to be found in the instant disclosure on pages 7-9. However, no *ipsis verbis* or implied support can be located to support the concept of a pressure-sensitive adhesive layer consisting of four elements: fentanyl, a pressure-sensitive adhesive base, a percutaneous absorption enhancer and a tackifier resin. In the working examples, the pressure sensitive adhesive layers consist of fentanyl, a pressure-sensitive adhesive base (SIS and PIB), a tackifier (Acron P-100™), liquid paraffin and aluminum silicate. In paragraph [0045] of the published disclosure, liquid paraffin is taught as an optional ingredient to adjust the pressure sensitive adhesive layer. The disclosure does not mention liquid paraffin as a percutaneous absorption enhancer. There is also no explicit or implicit teaching or

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suggestion that aluminum silicate is a percutaneous absorption enhancer. In paragraphs [0023, 0040 and 0041] of the instant published disclosure, percutaneous absorption enhancers are listed as genus compounds, such as fatty alcohols, ethers, aromatic alcohols, as well as specific compounds recited in instant claim 9. However, no support can be found for a pressure-sensitive adhesive layer that consists of fentanyl, a pressure-sensitive adhesive base, a percutaneous absorption enhancer and a tackifier resin. Applicant is required to point out support for this concept or cancel the new matter presented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8, 9, 11, 12, 14-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (US 6,139,866), Tsuruda et al. (CA 2 424 579), Hirano et al. (US 6,495,159) and Higo et al. (US 5,866,157).

Chono et al. disclose an adhesive patch comprising a backing layer and a pressure-sensitive adhesive layer formed on one side thereof (col. 5, lines 39-43), wherein the pressure-sensitive adhesive layer comprises a pressure-sensitive adhesive base (col. 5, lines 19-22). The inclusion of a percutaneous absorption enhancer in the pressure-sensitive adhesive layer is one or more selected from a group consisting of isopropyl myristate and oleyl alcohol (col. 4, lines 6-8, 22-23). Chono et al. disclose fentanyl as an active ingredient in the concentration of 5% by weight, see Example 6. Chono et al. further teach the inclusion of a tackifier, Arcon P-100, see

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col. 3, lines 44-53. It is well known in the art that Arcon P-100 is an alicyclic saturated hydrocarbon resin, as evidenced by Higo et al. (Example 2). The pressure-sensitive adhesive base of Chono et al. comprises polyisobutylene and a styrene/isoprene/styrene block copolymer. Chono et al. discloses the weight ratio of polyisobutylene to styrene/isoprene/styrene is in the range of 1:1 and 1:4 (col. 3, lines 9-10), which encompasses the instant ratios. However, the instant claims require that the PIB be between 8-15 wt %. Chono et al. fails to disclose these weight percent ranges.

However, Tsuruda et al. disclose an adhesive patch having combination of styrene/isoprene/styrene block copolymer and polyisobutylene (pg. 23, lines 20-24). Tsuruda et al. disclose the total amount of polyisobutylene be in the range of 1-20% by weight (pg. 21, lines 9-13). This range taught by Tsuruda et al. would include ranges between 8-15 wt %. Tsuruda et al. also teach that the amount of styrene/isoprene/styrene block copolymer being in the range of 15-30% by weight (pg. 20, lines 16-21).

From the teachings of Tsuruda et al., one of ordinary skill in the art at the time the invention was made would have chosen any particular combination of PIB and SIS within the ranges taught to arrive at a specific ration, including a 2:3 ration or a 3:2 ration, or any range between the two. It would have been an obvious design choice to one of ordinary skill in the art to modify the amount of the polymers, as desired, in order to adjust the adhesive strength and adhesion properties, as taught by Tsuruda et al. (pg. 23, line 10 - pg. 24, line 20). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discover the optimum or working ranges involves only routine skill in the art (emphasis added). *In re Aller*, 105 USPQ 233. In the instant case, Chono et al. teaches that the instant ratios between PIB:SIS

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are 1:1, which teaches the ratios used in the instant examples 1-4 on page 20 of the instant disclosure. Regarding the obviousness of attaining ratios ranging from 2:3 and 3:2, as instantly recited, both Chono et al. and Tsuruda et al. teach varying ratios between PIB and SIS. Additionally, Tsuruda et al. teaches weight percentages of each ingredient that would have rendered the ratio range instantly claimed *prima facie* obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

In addition, Tsuruda et al. discloses an adhesive patch having a styrene/isoprene/styrene block copolymer and a combination of polyisobutylenes having high and low molecular weights, wherein the low molecular weight polyisobutylene is Vistanex LM-MH and the high molecular weight polyisobutylene is Vistanex MML-100 (pg. 21, lines 9-24; pg. 22, lines 10-12). It would have been obvious to one of ordinary skill in the art to utilize a combination of polyisobutylenes having high and low molecular weights in the adhesive patch of Chono et al. to improve adhesive strength, increase the length of time of adhesion to the skin and improve pain at the time of peeling, see page 22, lines 19-24 of Tsuruda et al.

Regarding the instantly required tackifier resin, Chono et al. disclose the tackifier resin being in the range from 5-50% by weight (col. 3, lines 56-60). Example 7 of Chono et al. demonstrates an adhesive patch of a similar composition having a tackifier resin at 32% by weight. It would have been obvious to one of ordinary skill in the art to modify the range of the tackifier resin, as desired, in order to regulate the viscosity and adhesive strength of the adhesive base, as taught by Tsuruda et al. (pg. 25, lines 9-25). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discover the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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Chono et al., Tsuruda et al. and Higo et al. do not teach a tackifier resin to be hydrogenated petroleum resin.

However, Hirano et al. teach an adhesive patch comprising a tackifier resin of hydrogenated petroleum resin, see column 6, lines 4-17.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the hydrogenated petroleum resin of Hirano et al. in the adhesive patch of Chono et al., Tsuruda et al. and Higo et al. since Hirano et al. specifically teach hydrogenated petroleum resin as a conventional alternative to Acron P-100™, see column 6, lines 4-17 of Hirano et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for using the hydrogenated petroleum resin of Hirano et al. in the adhesive patch of Chono et al., Tsuruda et al. and Higo et al. because Hirano et al. and Chono et al., Tsuruda et al. and Higo et al. teach that the tackifier resin as a component of a pressure sensitive adhesive that is used in an amount of no more than 50% weight of the adhesive patch, see column 6, lines 4-17 of Hirano et al. and column 3, lines 56-60 and Example 7 of Chono et al.

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al., Tsuruda et al., Higo et al. and Hirano et al. as applied to claims 1-3, 8, 9, 11, 12, 14-16 and 19 above, and further in view of Urquhart et al. (US 4,031,894).

See the teachings of Chono et al., Tsuruda et al., Higo et al. and Hirano et al. above. None of the references teach the average molecular weight of the high molecular weight polyisobutylene as being in the range of 900,000-2,500,000. Nevertheless, it is well known in

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the art that Vistanex MML-100 has an average molecular weight about 1,200,000, as evidenced by Urquhart et al. (col. 6, lines 10-12), thus is in the range of 900,000-2,500,000.

Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al., Tsuruda et al., Higo et al. and Hirano et al. as applied to claims 1-3, 8, 9, 11, 12, 14-16 and 19 above, and further in view of Scholz et al. (US 5,750,136).

See the teachings of Chono et al., Tsuruda et al., Higo et al. and Hirano et al. above. None of the references teach the average molecular weight of the low molecular weight polyisobutylene being in the range of 30,000 – 65,000. Nevertheless, it is well known in the art that Vistanex LMMH has an average molecular weight about 53,000, as evidenced by Scholz et al. (col. 6, lines 21-23), thus is in the range of 30,000 – 65,000.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al., Tsuruda et al., Higo et al. and Hirano et al. as applied to claims 1-3, 8, 9, 11, 12, 14-16 and 19 above, and further in view of Zaffaroni (US 3,598,122) and Kochinke (US 5,350,581).

See the teachings of Chono et al., Tsuruda et al., Higo et al. and Hirano et al. above. None of the references teach the adhesive patch having an area of 10-75 cm². Zaffaroni discloses utilizing a transdermal bandage having a surface area of 0.5 to 400 cm², where the size is dependent on the activity of the drug and the rate of its absorption through the skin (col. 6, lines 25-29). It would have been an obvious design choice to one of ordinary skill in the art to modify the surface area of the adhesive patch in order to ensure that the amount of drug entering the system appropriate for the treatment was safe and efficacious, as taught by Kochinke (US 5,350,581) (col. 1, lines 17-20).

Response to Arguments

Applicant cites MPEP § 2144.05, which states that if a reference range broadly encompasses a large number of possible distinct compositions, this might present a situation similar to the obviousness of a species within a broad genus taught by the prior art. In the instant case, applicant points out that Chono et al. teach a broad range of tackifiers ranging from 0.1-70%, 5-50% or 10-35%. Applicant also points out that Tsuruda et al. and Higo et al. also teach a broad range of tackifiers present between 5-50% and 10-70%, respectively. In comparison, the instant claims require the tackifier resin to be present between 40-50%. Applicant asserts that for these reasons, the broad genus of adhesives taught in the prior art do not render the invention obvious.

Applicant further argues that the instant invention demonstrates criticality and an unexpected result for using a tackifier resin of not more than 50% and not less than 40% on page 7 of the instant application. Applicant asserts that these teachings obviate the broad ranges of tackifiers used in the prior art cited.

Applicant's arguments and a review of the references have been fully considered, but are found unpersuasive. Tsuruda et al. specifically state on page 25, lines 21-25:

"A base containing [*tackifier*] more than 50% by mass is not preferable because it will lower [*sic*] shape retention and increase [*sic*] pain at the time of peeling, damage to the keratin layer, skin eruptions, stickiness and so on."

Therefore, Tsuruda et al. provide explicit reasoning in the prior art at the time the invention was made to ordinary artisans to avoid using more than 50% of tackifier in an adhesive patch.

In addition, Hirano et al. teach using 50.0% tackifier resin in the adhesive patch in Example 7.

Regarding obviousness of the lower end of the instant range claimed, i.e. 40%, ten out of fifteen working examples conducted by Chono et al. comprise approximately 40% of tackifier resin in the adhesive patch disclosed, see Examples 4 and 7-15. In addition, Higo et al. teach using 37.5% of tackifier resin in the adhesive patch, see Example 19.

Therefore, the instant rejection over the teachings of Chono et al., Tsuruda et al., Higo et al. and Hirano et al. meet the standard of rendering the instant species range prima facie obvious under the discussions provided in MPEP § 2144.05 since the narrow range instantly claimed were applied within the working examples of Chono et al., Hirano et al. and Higo et al., and Tsuruda et al. provides explicit teaching for using less than 50% tackifier. It is clear that no surprise or unexpected result would occur among those of ordinary skill in the art at the time the invention was made using the instant narrow range of tackifier claimed in an adhesive patch.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on M-F 5:30 AM-3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
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